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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,608	03/15/2004	Stephen Truesdale Carney		1797

7590 01/13/2006

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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/800,608	Applicant(s) CARNEY, STEPHEN TRUESDALE	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 are pending in the application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'to reduce certain risk factors of cardiovascular disease'. Which risk factors are these? Because the ordinary artisan could not ascertain which risk factors Applicant is referring to, the claim is deemed indefinite. Clarification is necessary. Claim 1 further recites 'in an amount of 540 mg twice daily'. This phrase is considered ambiguous; does it mean that 540 mg is administered only in a day, and that this amount is split in two for administration of the product 'twice daily'; or does it mean that 540mg is given twice daily? Clarification is necessary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Vitacost.com (2002).³

Vitamin supplements containing essential nutrients such as Vitamin B-6, B-12, Vitamin C and folic acid were well known in the art at the time the invention was made. Vitacost.com (2002)³ for example, sold a supplement comprising 500mg of Vitamin C, 800 mcg folic acid, 500 mcg Vitamin B-12 and 50 mg of Vitamin B-6 (see pp. 1-2 of 'Synergy' multi-vitamin caps (caplet)).

Vitamin C is an 'essential nutrient' according to 'The World's Healthiest Foods; Feeling great internet site (p. 1). It is noted that Vitamin C (ascorbic acid) is an intrinsic vitamin to alfalfa sprouts, thereby rendering obvious 'essential nutrients from alfalfa sprouts' (see list of phytochemicals/nutrients intrinsic to alfalfa according to Dr. Duke's Phytochemical and Ethnobotanical Databases, pp. 1-6/page 1 lists 'ascorbic-acid' among one of many intrinsic nutrients).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art do not teach all the various permutations of claimed concentration ranges, it would be conventional and within the skill of the art to identify the optional concentrations of a given excipient because the selection of appropriate concentration of vitamins in multi-vitamin compositions was routinely optimized for age, weight and sex.

It was routine in the art of neutricutical manufacture to produce nutritional compositions which were in varying dissolvable forms. The encapsulation process was beneficial in delivering active ingredients with reduced potential of being degraded in the stomach, thereby allowing the active ingredients to reach the small intestine to provide increased bioavailability of said active ingredients (i.e.; sustained release). Thus, one of ordinary skill in the art would have been motivated to have formulated the 'Synergy'

multi-vitamin capsules as an extended release in order to increase efficacy of the composition.

Further, the form of the composition i.e.; dried or liquid, does not change the overall effect of the active ingredients, nor does it materially change the composition as a whole. Variations of nutritional forms such as powders, elixirs, beverages, or snack bars would have all been suitable packaging means for the active ingredients of the Instant invention, or the prior art invention and would not have required a substantial inventive contribution in order to have created these forms of the composition for ease of administration and/or to enhance the manufacturability of the product (to make the product more appealing to the consumer).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

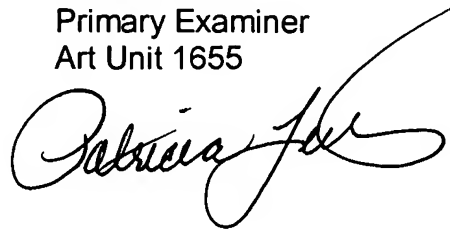
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized flourish extending from the end of the signature.

01/03/05